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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
DUFFY, PATRICIA ANN	

ART UNIT	PAPER NUMBER
1645	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/586,932	DEFOOR ET AL.	
	Examiner	Art Unit	
	Patricia A. Duffy	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *18 September 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *37-82* is/are pending in the application.

4a) Of the above claim(s) *61-82* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *37-60* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

RESPONSE TO AMENDMENT

The amendment and response filed 9-18-08 has been entered into the record. Claims 1-36 have been cancelled. Claims 37-82 are pending. Claims 37-82 are under examination.

The text of Title 35 of the U.S. Code not reiterated herein can be found in the previous office action.

Newly submitted claims 61-82 are directed to an invention that lack unity of invention from the nucleic acid and nucleic acid construct of claims 37-60 from the invention originally claimed for the following reasons: The cell product and method of using the cell product lack unity of invention with the nucleic acids, because the nucleic acid does not define a technical feature over the art and therefore does not meet the criteria of PCT Rule 13.2. Consequently, the additional products and methods lack unity of invention with the examined invention.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 61-82 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Rejections Maintained

Claims 37-60 stand rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement for reasons made of record in the Office Action mailed 4-18-08.

Applicant's arguments have been carefully considered but are not persuasive. Applicants argue that there would be a high correlation of structure in function among the 90% identical polypeptides. This is not persuasive because Applicants describe and characterize ysbC the specification at page 1, "A search in the public databases for any

polypeptide having amino acid homology to the orotate transporter of the present invention, revealed that the closest polypeptide had less than 35% sequence identity, and it was completely unrelated to the orotate transporter of the present invention. Consequently, the ysbC-encoded orotate transporter represents **a completely pioneering new class of molecules** [emphasis added]. The claims encompass a vast array of nucleic acid and protein variants from a wide variety of different organisms (see pages 11-15 of the specification) which is described as pioneering in nature. As such, the art therefore does not recognize a correlation of the structure of the protein with the function of "orotate transport" and the specification does not describe a number of the new genus such that the skilled artisan would readily appreciate the correlation of structure with function of orotate transport. Applicants argue that the specification at page 14 teaches how to make substitutions and one would clearly recognize variants of 90% identity were in Applicants possession. This is not persuasive; the claims require 90% identity and orotate transporter activity and suitable for use in a cell that is pyrimidine ouxotrophic. The correlation of the particular structural requirements with orotate transporter activity is not set forth in the specification and the specification does not set forth those regions that are, or are not critical to the function of the orotate transporter. The structural requirement(s) for "suitable for use in a cell that is pyrimidine ouxotrophic" is not set forth in the specification. Specific not general guidance is what is needed and the ability to screen for functional variants as set forth on page 14 of the specification is not the standard for written description.

A written description of an invention involving a chemical genus, like a description of a chemical species, 'requires a precise definition, such as by structure, formula, [or] chemical name,' of the claimed subject matter sufficient to distinguish it from other materials." *University of California v. Eli Lilly and Co.*, 119 F.3d 1559, 1568, 43 USPQ2d 1398, 1405 (Fed. Cir. 1997 (bracketed material in original). The claims in *Lilly* were directed generically to vertebrate or mammalian insulin cDNAs. *See id.* at 1567,

43 USPQ2d at 1405. The court held that a structural description of a rat cDNA was not an adequate description of these broader classes of cDNAs.

The *Lilly* court explained that a generic statement such as... 'mammalian insulin cDNA,' without more, is not an adequate written description of the genus because it does not distinguish the claimed genus from others, except by function. It does not specifically define any of the genes that fall within its definition. It does not define any structural features commonly possessed by members of the genus that distinguish them from others. One skilled in the art therefore cannot, as one can do with a fully described genus, visualize or recognize the identity of the members of the genus. Id. at 1568, 43 USPQ2d at 1406. Finally, the *Lilly* court set out exemplary ways in which a genus of cDNAs could be described: A description of a genus of cDNAs may be achieved by means of a recitation of a representative number of cDNAs, defined by nucleotide sequence, falling within the scope of the genus or of a recitation of structural features common to the members of the genus, which features constitute a substantial portion of the genus. *Id.* at 1569. *"Eli Lilly* did not hold that all functional descriptions of genetic material necessarily fail as a matter of law to meet the written description requirement; rather, the requirement may be satisfied if in the knowledge of the art the disclosed function is sufficiently correlated to a particular, known structure." *Amgen, Inc. v. Hoechst Marion Roussel, Inc.*, 314 F.3d 1313, 1332, 65 USPQ2d 1385, 1398 (Fed. Cir. 2003). A biomolecule described only by a functional characteristic (i.e. orotate transport, suitable for use in a pyrimidine auxotrophic cell), without any known or disclosed correlation between the biological function and the structure of the molecule is not a sufficient identifying characteristic for written description purposes, even when accompanied by a method of obtaining the claimed sequence. *In re Bell* F.2d 781, 26 USPQ2d (Fed. Cir. 1993). Further, the court in *Enzo Biochem v. Gen-Probe, Inc.*, 323 F.3d 956, 964 (Fed. Cir. 2002) ("Enzo Biochem II"), stated that "the written description requirement would be met for all of the claims [of

the patent at issue] if the functional characteristic of [the claimed invention was] coupled with a disclosed correlation between that function and a structure that is sufficiently known or disclosed." Ibid. at 1513. The *Enzo* court held that a claimed DNA could be described without, necessarily, disclosing its structure. The court adopted the standard that "the written description requirement can be met by 'show[ing] that an invention is complete by disclosure of sufficiently detailed, relevant identifying characteristics.., i.e., complete or partial structure, other physical and/or chemical properties, functional characteristics when coupled with a known or disclosed correlation between function and structure, or some combination of such characteristics.'" *See id.* at 1324, 63 USPQ2d at 1613 (emphasis omitted, ellipsis and bracketed material in original). This standard applies to polypeptides as well as DNAs. *See University of Rochester v. G.D. Searle & Co., Inc.*, 358 F.3d 916, 925, 69 USPQ2d 1886, 1893 (Fed. Cir. 2004): "We agree with Rochester that *Fiers, Lilly, and Enzo* differ from this case in that they all related to genetic material whereas this case does not, but we find that distinction to be unhelpful to Rochester's position. It is irrelevant; the statute applies to all types of inventions. We see no reason for the rule to be any different when non-genetic materials are at issue." With respect to the use of an assay to support written description, in *University of Rochester*, the patent claimed a method of selectively inhibiting the enzyme PGHS-2 (also known as COX-2) by administering a non-steroidal compound that selectively inhibits activity of the PGHS-2 gene product to a human." *Id.* at 918, 69 USPQ2d at 1888. The patent "describes in detail how to make cells that express either COX-1 or COX-2, but not both..., as well as 'assays for screening compounds, including peptides, polynucleotides, and small organic molecules to identify those that inhibit the expression or activity of the PGHS-2 gene product.[']" *Id.* at 927, 69 USPQ2d at 1895. The court held that the disclosure of screening assays and general classes of compounds was not adequate to describe compounds having the desired activity: without disclosure of *which* peptides, polynucleotides, or small organic molecules have the desired characteristic, the claims failed to meet the description

requirement of § 112. *See id.* ("As pointed out by the district court, the '850 patent does not disclose just 'which "peptides, polynucleotides, and small organic molecules" have the desired characteristic of selectively inhibiting PGHS-2.'... Without such disclosure, the claimed methods cannot be said to have been described."). For the foregoing reasons, the claims lack written description.

Claims 37-60 stand rejected under 35 U.S.C. 102(b) as being clearly anticipated by Bolotine et al (FR 2807446, published October 10, 2001; pages 1-87, 120, 183, and 198-217 only) for reasons made of record in the Office Action mailed 4-18-08.

Applicant's amendments do not obviate the rejection of record. Suitable for use in a pyrimidine auxotrophic cell does not structurally define the nucleic acid over the prior art. Applicant has not addressed the interpretation of the claims with respect to the "an amino acid sequence" reading on a fragment that is 100% identical. Further, Applicant's arguments do not comply with 37 CFR 1.111(c) because they do not clearly point out the patentable novelty which he or she thinks the claims present in view of the state of the art disclosed by the references cited or the objections made. Further, they do not show how the amendments avoid such references or objections.

Status of Claims

Claims 37-60 stand rejection. Claims 61-82 are withdrawn from consideration.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Patricia A. Duffy whose telephone number is 571-272-0855. The examiner can generally be reached on M-Th 7:30 am - 6:00 pm. If attempts to reach the examiner by telephone are unsuccessful, the examiner's Supervisors, Robert Mondesi can be reached at 571-272-0956.

The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

/Patricia A. Duffy/
Primary Examiner